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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,837	12/07/2005	Soojin Lee	CMT-0016	2897

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EXAMINER	
NGUYEN, QUANG	
ART UNIT	**PAPER NUMBER**
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,837	LEE ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-36 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Group Restriction

Group I, claims 1-11, drawn to an isolated nucleic acid molecule selected from a Markush group recited in claim 1, a vector, a host cell comprising the same **and a first method** for producing a polypeptide using the same.

Group II, claims 12-13, 21, 33, drawn to an isolated polypeptide or protein of the present invention or a composition comprising the same, and **a first method** of identifying binding partners for a protein of the present invention comprising the steps of exposing the protein to a potential binding partner and determining if the potential binding partner binds to said protein.

Group III, claims 14-15, drawn to an isolated antibody or antigen-binding antibody fragment that binds to a polypeptide of the present invention.

Group IV, claims 16 and 19, drawn to a method of identifying an agent which modulates the expression of a nucleic acid encoding a protein of the present invention comprising the step of exposing cells which express the nucleic acid to the agent and determining whether an agent modulates the expression of said nucleic acid.

Group V, claims 17-18 and 20, drawn to a method of identifying an agent which modulates the level of or at least one activity of a protein of the present invention comprising the steps of exposing cells which express the protein to the agent and determining whether the agent modulates the level of or at least one activity of said protein.

Group VI, claims 22-23, drawn to a method of identifying an agent which modulates the interaction between a binding partner and a protein of the present invention comprising the steps of exposing said protein with said partner to the agent and determining whether the agent modulates association of the binding partner with said protein.

Group VII, claims 24-25, drawn to a non-human transgenic animal modified to contain a nucleic acid molecule of the present invention.

Group VIII, claims 26-28, drawn to a method of treating a disease in a subject comprising inserting into a diseased cell a gene construct comprising an isolated nucleic acid molecule of the present invention, wherein said inserting into a diseased cell is accomplished *in vivo*.

Group IX, claims 26 and 28, drawn to a method of treating a disease in a subject comprising inserting into a diseased cell a gene construct comprising an isolated nucleic acid molecule of the present invention, wherein said inserting into a diseased cell is accomplished *in vitro*.

Group X, claims 29-32, drawn to a method of diagnosing a disease state in a subject comprising determining the level of expression of a nucleic acid molecule of the present invention.

Group XI, claims 34-36, drawn to a method of diagnosing a disease state in a subject comprising determining the level of expression of a protein of the present invention.

The currently claimed subject matter, Inventions of Groups I-XI, lack unity of invention according to Rule 13.1 PCT for the following reasons.

The isolated nucleic acid molecules of Group I, the isolated polypeptides or proteins of Group II, the isolated antibodies or antigen-binding antibody fragments of

Group III, the non-human transgenic animals of Group VII are compositions that are different chemically one from the others, as well as each composition has different properties and/or characteristics one from the others. For examples, the polypeptides of Group II are made up of amino acid residues and different in the primary sequences from the antibodies of Group III. The isolated nucleic acid molecules of Group I are made up of nucleotides. The transgenic non-human animals of Group VII are living entities, physically and chemically different from the other compositions. **Therefore, each of the above compositions does not share the same technical feature, and accordingly the compositions lack the same or corresponding special technical features.**

The methods in Groups I-II, IV-VI and VIII-XI are different one from the others by having different starting materials, different method steps and different desired end-results. For examples, **the first method of use** in Group I is directed to a method for producing a recombinant polypeptide of the present invention; **the first method of use** in Group II is drawn to a method for identifying binding partners for a protein of the present invention by exposing the protein to a potential binding partner; the method in Group IV is for identifying an agent which modulates the expression of a nucleic acid encoding a protein of the present invention; the method of Group V is for identifying an agent which modulates the level of or at least one activity of a protein of the present invention; the method of Group VI is for identifying an agent which modulates the interaction between a binding partner and a protein of the present invention; the treatment methods in Groups VIII-IX are drawn to *in vivo* gene therapy and *ex vivo* gene

therapy methods, respectively; the method of Group X is directed to a diagnosing method by determining the level of expression of a nucleic acid molecule of the present invention; and the method of Group XI is for diagnosing a disease state in a subject by determining the level of expression of a protein of the present invention. **Each different method step can be considered to be a "special technical feature"; and therefore the methods listed in Groups I-II, IV-VI and VIII-XI lack the same or corresponding special technical features.**

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Additionally, please note that different nucleotide sequences are structurally different chemical compounds and are unrelated to one another (In effect, these different nucleotide sequences lack the same or corresponding technical feature). These sequences, for this instance nucleic acid molecules with SEQ ID NOS: 1, 3, 5, 7, 9, 11, 13 and 15 or their respective encoding amino acid sequences with SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14 and 16, are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C 121. Absent evidence to contrary, each such nucleotide sequence is

presumed to represent an independent and distinct invention, select to a restriction requirement pursuant to 35 U.S.C. 121 and CFR 1.141 et seq.

It has been decided that, due to the high burden on the Office to search sequences ONE sequence constitutes a reasonable number for examination purposes. **Applicant is further required to elect ONE independent and distinct sequence.** Examination will be restricted to only the one elected sequence within each elected Group. The search of no more than one selected sequences may include the complements of the selected sequence and where appropriate, may include subsequences within the selected sequence (e.g., oligomeric probes and/or primers).

Species Restriction

Should Applicants elect Group X, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. ***A single specifically named malignant neoplasm recited in the Markush group of claim 32.***

Applicant is required, in reply to this action, **to elect a single species consistent to the elected invention** to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims

readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Each of the malignant neoplasm species recited in claim 32 is different structurally and has different underlying causes and disease progression one from the others; and therefore the listed species lack the same or corresponding special technical features.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

QUANG NGUYEN, PH.D.
PRIMARY EXAMINER